Press Release
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Affibody's Partner ACELYRIN Announces Positive Top-line Results for Izokibep in Psoriatic Arthritis and Long-Term Clinical Benefits in Hidradenitis Suppurativa

- Phase 2b/3 psoriatic arthritis clinical trial met the primary endpoint of ACR50 at 16 weeks versus placebo with high statistical significance. Robust responses were achieved for ACR70, PASI100, ACR50/PASI100, and Minimal Disease Activity.
- Long-term 32-week data from Phase 2b hidradenitis suppurativa study demonstrated sustained responses and deepening clinical benefit. Deep and consistent responses were observed for placebo patients switching to active treatment.
- Favorable safety profile of izokibep was confirmed in both trials, consistent with the IL-17A class and previous izokibep experience.

Solna, Sweden, March 11, 2024. Affibody's partner ACELYRIN, INC. today announced that the global Phase 2b/3 clinical trial of izokibep in psoriatic arthritis (PsA) met its primary endpoint with high statistical significance. Positive long-term data from a Phase 2b clinical trial in hidradenitis suppurativa (HS) were also announced.

In the Phase 2b/3 PsA trial the primary endpoint of ACR50 at week 16 was met with high statistical significance. Robust clinical responses were also achieved for ACR70, PASI100, as well as composite endpoints ACR50/PASI100 and Minimal Disease Activity.

Izokibep was well-tolerated with a favorable safety profile consistent with previous experience and the IL-17A class. The PsA trial had a low study discontinuation rate of less than 3%. Mild-to-moderate injection site reactions (ISRs) were observed with discontinuations due to ISR less than 2%.

"It is encouraging to see the positive effect of izokibep in these hard to treat patients. Deep responses have been reported with izokibep across indications. High orders of response such as ACR70 in PsA and HiSCR100 in HS demonstrate the unique ability of izokibep to help patients otherwise inadequately treated," said Affibody Chief Medical Officer, Nikolai Brun.

In PsA, ACELYRIN expects the reported Phase 2b/3 trial to be the first of two registrational trials.

In addition, ACELYRIN today announced long-term data from a Phase 2b HS trial. The data demonstrated that continued treatment with izokibep led to further clinical improvements over time with maintained favorable safety profile. These results are from an open label extension and include all subjects through week 32.

Patients who switched from placebo to izokibep at week 16 achieved a similar speed and magnitude of response, as those who began treatment with izokibep at baseline, for HiSCR, draining tunnels, skin pain, and Dermatology Life Quality Index. High orders of HiSCR were achieved with the majority of patients achieving HiSCR75 and about a third achieving HiSCR100 by week 16 and through 32 weeks.

“We are pleased to see the exciting results – especially the robust placebo cross-over responses – from this long-term follow up in HS, despite the initial primary endpoint of this study not meeting statistical significance. The HS data together with the positive data in PsA bolsters our excitement for izokibep and confirms izokibep as a leading candidate among the next generation IL-17 treatments,” said David Bejker, CEO of Affibody. “Izokibep continues with strong momentum and we look forward to additional readouts during the year from ongoing late-stage trials.”

Topline data from an ongoing Phase 3 HS trial (NCT05905783) are expected by the end of 2024. ACELYRIN plans an additional Phase 3 trial in HS of approximately 400 patients to address FDA guidance on size of safety database.

Further data from the PsA and HS trials will be presented at future scientific meetings. Additional information about the results can be found at ACELYRIN.com.

About the Phase 2b/3 Psoriatic Arthritis clinical trial
The Phase 2b/3 clinical trial (NCT05623345) is a global, multi center, randomized double-blind, placebo-controlled, trial evaluating the safety and efficacy of izokibep dosed subcutaneously 160 mg every week (QW) or every two weeks (Q2W) and 80 mg every four weeks (Q4W) versus placebo. 351 adult patients with active PsA were enrolled across 71 sites in the United States and Europe and randomized across the four arms. Dose sequencing in the 160 mg Q2W and 80 mg Q4W arms was impacted by a third-party programming error. The range of pharmacokinetic data from both the 160 mg QW and Q2W arms in PsA demonstrated comparable exposures to the same dose levels from the Phase 2b HS study.

For more information about the Phase 2b/3 PsA clinical trial, please visit www.clinicaltrials.gov.

About the Phase 2b Hidradenitis Suppurativa clinical trial
The Phase 2b clinical trial (NCT05355805) is a global, multi center, randomized double-blind, placebo-controlled, trial evaluating the safety and efficacy of izokibep dosed subcutaneously 160 mg every week (QW) or every two weeks (Q2W) versus placebo. At week 16, patients who received placebo were randomized to either the weekly or every two-week active treatment arm and all patients were assessed through week 32. The objective of the study was to determine the effect of izokibep versus placebo on various measures of clinical impact and determine the appropriate dose(s) for further clinical development in hidradenitis suppurativa.

For more information about the Phase 2b HS clinical trial, please visit www.clinicaltrials.gov.

About Psoriatic Arthritis

Psoriatic Arthritis (PsA) is a chronic immune-mediated inflammatory disease characterized by multiple manifestations including joint inflammation, skin lesions (psoriasis), and enthesitis (painful inflammation of the tissues that connect ligament and tendons to bone), all contributing to reduced quality of life and the risk of permanent disability. The pathology is dominated by pro-inflammatory T-helper (Th-17) cells that lead to over expression of IL-17, IL-23, and TNF cytokines. It is estimated that approximately 30% of people currently living with psoriasis will develop PsA over time. There remains a large unmet need for more effective therapies to treat PsA across all disease manifestations.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease causing scarring, abscesses, malodor, and severe pain. HS typically occurs in areas with high concentrations of sweat glands and is typically accompanied by pain, malodor, drainage, and disfigurement that contribute to disability and a devastating impact on quality of life. Patients with HS miss a greater number of days of work and have increased disability compared to the average population.

HiSCR measures response to treatment in HS with HiSCR50 indicating at least a 50% reduction in total abscess and inflammatory nodule count (AN count), with no increase in abscess count, and no increase in draining fistula count relative to baseline. Higher orders such as HiSCR75, HiSCR90, and HiSCR100 indicate 75%, 90%, and 100% reduction respectively.

About izokibep

Izokibep is small protein Affibody® therapeutic designed to inhibit IL-17A with high potency through tight binding affinity, the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody, and an albumin binding domain that results in improved pharmacokinetic (PK) properties. Clinical trial data support the hypothesis that these unique characteristics of izokibep may provide clinically meaningful and differentiated benefits for patients, including resolution of key manifestations of disease.

Izokibep is being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

Affibody has licensed izokibep, to ACELYRIN, INC. and Inmagene Biopharmaceuticals Co. Ltd., while retaining an option to co-promote in the Nordic region.

About Affibody® molecules

Affibody® molecules are a novel drug class of small therapeutic proteins with characteristics surpassing monoclonal antibodies (mAbs) and antibody fragments. The Company has created a large library consisting of more than ten billion Affibody® molecules, all with unique binding sites, from which binders to given targets are selected. Affibody® molecules are only 6 kDa in size.

They have demonstrated clinical utilities both as tumor-targeting moieties through their small size and as efficacious disease blocking agents in autoimmune indications by utilizing the inherent properties that allow multi-specific formats.

About Affibody

Affibody is a clinical stage integrated biopharmaceutical company with a broad product pipeline focused on developing innovative bi- and multi-specific next generation biopharmaceutical drugs based on its unique proprietary technology platform, Affibody® molecules.

Through its validated business model, the company has a proven capability of identifying and prioritizing strategic projects in a timely and de-risked way. Affibody has established several partnerships for the development and commercialization of its innovations with international pharmaceutical companies.

Affibody's main shareholder Patricia Industries is a part of Investor AB.

Further information can be found at: www.affibody.com.

Disclaimer

This press release contains forward-looking statements. While Affibody consider the projections to be based on reasonable assumptions, these forward-looking statements may be called into question by several hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements.

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Attachments

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